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Guidance for the Reregistration of Pesticide Products Containing Potassium Bromide (KBr) as the Active Ingredient Case Number 342

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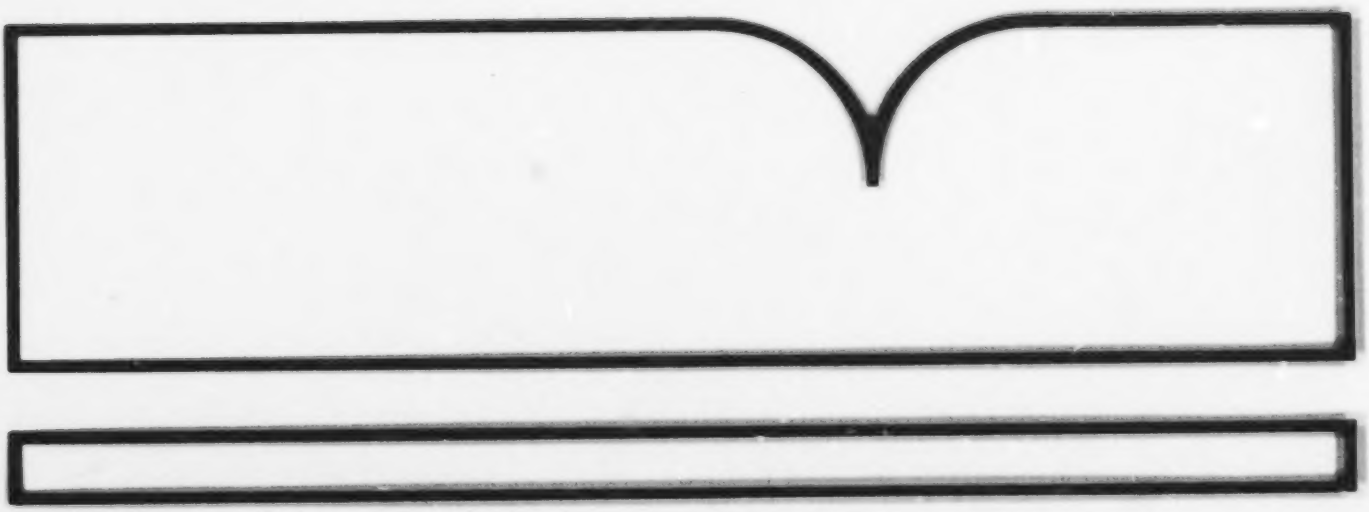

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GUIDANCE FOR THE REREGISTRATION OF PESTICIDE PRODUCTS

CONTAINING

POTASSIUM BROMIDE (KBr)

AS THE ACTIVE INGREDIENT

Case Number 342

ENVIRONMENTAL PROTECTION AGENCY
OFFICE OF PESTICIDE PROGRAMS

WASHINGTON, D.C. 20460

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INTRODUCTION

The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA Section 3(g)),as amended in 1978, directs EPA to reregister all pesticides as expeditiously as possible. Each registrant of a manufacturing use product of the active ingredient who wishes to continue to sell or distribute that product must apply for reregistration.

To fulfill this Congressional mandate, we have established the Registration Standards program which will review all pesticide active ingredients first registered before January 1, 1977. These pesticides will be reviewed in use clusters which are prioritized on the basis of a ranking scheme giving preference to pesticides used on food and feed crops.

The Registration Standards program involves a thorough review of the scientific data base underlying pesticide registrations and an identification of essential but missing studies which may not have been required when the product was initially registered or studies that are now considered insufficient. Our reassessment results in the development of a regulatory position, contained in this document, on each pesticide and its uses. The regulatory position may require the registrant to modify product labels to provide additional precautionary statements, restrict the use of the pesticide to certified applicators, provide reentry intervals, modify uses or formulation types, specify certain packaging limitations, or other requirements to assure that proper use of the pesticide poses no potential adverse effects to human health or the environment.

The scientific review, which is not contained herein but is available upon request, concentrates on the technical grade of the active ingredient and identifies missing generic data. However, during the review of these data we are also looking for potential hazards that may be associated with the formulated (end-use) products that contain the active ingredient. If we find serious concerns, we will bring formulated products under the provisions of the Registration Standards program to the extent necessary to protect the public.

EPA has the authority under FIFRA §3(c)(2)(B) to require that certain registrants submit generic data that will answer our questions regarding the hazard that may result from the intended use of the pesticide under review. Further, §3(c)(2)(B) provides that these data are to be submitted by those registrants who do not qualify for the formulator's exemption [FIFRA §3(c)(2)(D)]. Normally, this means that the registrants who are responsible for filling the data gaps are the manufacturing-use product producers (basic

suppliers of the active ingredient). However, end-use producers will not qualify for the formulator's exemption if the source of their active ingredient: (1) is not registered with EPA, and/or (2) is produced by the registrant's firm, or by a firm which has ownership in common with the registrant's firm. These end-use producers can qualify for the formulator's exemption if they change their source of supply to a registered source, provided the source does not share ownership in common with the registrant's firm. If the end-use product registrant decides to switch sources, a new Confidential Statement of Formula, EPA Form 8570-4, must be submitted to the appropriate Product Manager within 90 days of receipt of this Guidance Document. The chart on the following page shows what is generally required of those who do and do not qualify for the formulator's exemption in the Registration Standards program.

If you decide to request the Agency to discontinue the registration of any of your products subject to the reregistration requirements of this ;Guidance Document, please notify the Product Manager named in the cover letter, within 90 days from receipt of this document, that you wish to voluntarily cancel the registration(s). If you decide to maintain your product registration(s), you must provide the information described in the following pages within the time frames outlined. EPA will issue a notice of intent to cancel or suspend the registration of any currently registered product if you fail to comply with the requirements set forth in this Guidance Document.

This Guidance Document will be supplemented by EPA with additional information about compliance with data support requirements. In Union Carbide Agricultural Products Co., Inc. v Ruckelshaus, EPA was enjoined from permitting or implementing any use of data where the submitter's compensation is to be determined under Section 3(c)(1)(D) of the FIFRA. EPA is assessing the implications of the injunction for the reregistration process. Because this situation is currently unresolved, EPA has decided to proceed with those requirements in this Guidance Document which do not relate to compliance with the §3(c)(1)(D) provisions, and to supplement the document with additional guidance when circumstances permit. Failure to comply with the provisions of the subsequent guidance will also result in issuance by EPA of an intent to cancel the affected product registration(s).

Registrants are reminded that §6(a)(2) of FIFRA requires you at any time to submit factual information raising concerns of possible unreasonable adverse effects of a pesticide. You should notify the Agency of interim results of studies in progress if those results show possible adverse effects.

PRODUCTS SUBJECT TO THE REGISTRATION STANDARDS PROGRAM	ACTION(S) REQUIRED TO MAINTAIN REGISTRATION
I. Products That Do Not Qualify For The Formulator's Exemption	
A. Single Active Ingredient Products*	These products must be reregistered. To obtain reregistration, labeling, packaging and data requirements must be satisfied in accordance with the Registration Standards Guidance Document.
B. Multiple Active Ingredient Products	See Section C(1)(b) on page 7, and Section C(3)(b) on page 8 of this standard.
II. Products That Do Qualify For The Formulator's Exemption	Only when additional restrictions or labeling are needed to protect man or the environment will these products be subject to the Registration Standard requirements. Affected products will be dealt with in a variety of ways, including but not limited to the Label Improvement Program and special intent to cancel notices.

* End-use products of registrants who also produce a manufacturing-use product will not be required to be reregistered provided that registrant fulfills the requirements specified in the Guidance Document for manufacturing-use product(s). Such end-use products will be subject to the labeling changes required for products in "II" above. If there are no manufacturing-use products registered by any company end-use products will be required to be reregistered.

NOTE: If all registrants in "I" above fail to meet the requirements in I-A and B above, then the registrants in "II" lose their right to qualify for the formulator's exemption and become subject to the requirements in I-A and B.

II REGULATORY POSITION AND RATIONALE

A. INTRODUCTION

Registration standards describe the regulatory position and rationale for all registered manufacturing-use products (MUPs) containing the chemical under review as the sole active ingredient. End-use products (EUPs) are reviewed only when there are no MUPs registered or when a label is changed significantly. There are no registered MUPs containing Potassium Bromide as the sole active ingredient. Furthermore, there is only one registered end-use product (EUP) containing this chemical, and it contains two other active ingredients. Therefore this standard describes the regulatory position and rationale for the unregistered technical grade of Potassium Bromide (in the event a prospective registrant wishes to register it as an MUP), and for the only registered use appearing on the approved label of the registered product containing this chemical.

1. Manufacturing-Use Products (MUPs)

Potassium Bromide is not registered as a manufacturing-use product (MUP). The technical grade of the active ingredient is available as an unregistered material from chemical supply houses, at about 99% purity. The non-pesticidal uses for this chemical outnumber and outweigh in economic importance the pesticidal use. Therefore this standard is a modification of the usual standard: it applies to the approved uses of the only registered product containing this chemical, an end-use product containing multiple active ingredients.

2. End-Use Products (EUPs)

The registered product containing Potassium Bromide as an active ingredient is an end-use Product (EUP):

SAF-SOL Brand For Istitutional Use
EPA Registration No. 875-42
Diversey Wyandotte
1532 Biddle Ave
Wyandotte, MI 48192

The approved label for the registered product lists three active ingredients:

Sodium Hypochlorite	3.25%
Potassium Bromide	2.00%
Sodium Phosphate	89.75%

The product was registered on August 15, 1960, without any supporting acute toxicity data. The approved label bears the signal word WARNING, which places it in toxicity category II, most probably because the rpoduct contains 89.75% Sodium Phosphate, a chemical which may be irritating to eyes at this concentration.

B. DESCRIPTION OF THE CHEMICAL

Potassium Bromide is an old, well known inorganic chemical whose chemical and toxicological properties are extensively documented in the published literature. The Merck Index, 4th Edition, provides the following information for this chemical: KBr, molecular weight 119.01, Br 47.85%, K 23.41%, O 28.74%, colorless crystals or white granules, or powder; density 2.75, melting point 730°C; 1 gram dissolves in 1.5 ml water or in 250 ml alcohol. The aqueous solution is neutral. Human Toxicity: large doses cause central nervous system depression: prolonged intake may cause mental deterioration, acneform skin eruptions. Uses: sedative, anti-convulsant.

The Chemical Abstracts Service (CAS) Registry number is 7758-02-3: the EPA Chemical Code Number is 041101.

C. REGULATORY POSITION AND RATIONALE

After reviewing and evaluating the available data and other relevant information on Potassium Bromide, the Agency has made the following determinations with respect to the technical grade of the active ingredient (TGAI) 1/, and the end-use registered product.

1. Acute Toxicity

(a) Manufacturing-Use Products

The technical grade of Potassium Bromide has not been registered as a manufacturing-use product, even though the chemical appears as an active ingredient on labeling accepted for an end-use product. Therefore no one has submitted acute toxicity data for the TGAI to support registration as an MUP. Nevertheless, the Agency will not require generation of acute toxicity data to register the TGAI as an MUP unless the applicant or registrant fails to cite or submit relevant information from the published literature to establish the toxicity categories of the TGAI in accordance with Section 162.10 of Title 40 of the Code of Federal Regulations.

Rationale: In accordance with Pesticide Registration Notice 83-4 2/ and 83-4(A) 3/ a registrant has the option of satisfying a data requirement to register a pesticide by submitting or citing relevant data from the published literature instead of generating such data. In the case of the technical grade of Potassium Bromide a registrant should have no difficulty in submitting or citing information from the pubished literature on this chemical to satisfy at least some, if not all, of the acute toxicity data requirements, listed in Table A at the end of this chapter.

1/ For the purpose of this standard the technical grade of Potassium Bromide is defined as any material containing 99% KBr, and containing only those impurities generally associated with the manufacturing process, and generally considered as safe.

2/ Pesticide Registration Notice 83-4, June 16, 1984. Interim Procedures For Satisfying Registration Data Requirements Under Recent Court Actions.

3/ Pesticide Registration Notice 83-4(A), June 23, 1984. Supplement to PR Notce 83-4.

(b) End-Use Products

To reregister the end-use product cited in this standard the registrant must not only satisfy the product specific data requirements specified in Table B, but he or she must also satisfy the generic items of data pertaining to the technical grade of Potassium Bromide specified in Table A, at the end of this chapter. These include acute toxicity data and fish and wildlife data.

Rationale: The registrant of the end-use product cited in this standard uses an unregistered source of the technical grade of the active ingredient. This prevents the registrant from qualifying under the formulator's exemption as explained on page 1 of this standard, and in PR Notice 83-4 previously cited.

2. Chronic Toxicity

The Agency has concluded that none of the criteria for unreasonable adverse effects listed in Section 162.11 (a) of 40 CFR have been triggered or exceeded for the uses specified in this standard.

Rationale: A review of relevant information in the published literature 1/ on Potassium Bromide has raised no chronic or long term toxicological concerns for the approved pesticidal use. Furthermore, the registered use is as a final sanitizing rinse on food contact surfaces. Potassium Bromide, in combination with other chemicals generally recognized as safe, is cleared for this use as an incidental food additive under Section 178.1010 (b)(1) of Title 21 of the Code of Federal Regulations, which is administered by the Food and Drug Administration. Each end-use product proposed for this use must comply with the provisions of this section.

1/ Appendix III-1, GS-0342-003, Spencer, H. G. et al, Food Research, 9:11, 1944.

3. Ecological Effects

(a) Manufacturing-Use Products

To register the technical grade of Potassium Bromide as a manufacturing-use product a registrant must satisfy the data requirements specified in Table A at the end of this chapter.

Rationale: According to the guidelines 1/ the Agency requires toxicity data on fish, birds, and aquatic invertebrates to support the registration of all mamufacturing-use products.

(b) End-Use Products

(i) Registrants of end-use products who qualify under the formulator's exemption may register end-use products for the use specified in this standard without having to address or satisfy the data cited above.

Rationale: According to the guidelines, ecological effects data must be developed by testing the technical grade of the active ingredient or the manufacturing-use product. In order to be exempt from these data requirements and qualify under the formulator's exemption, the registrant of the end-use product must purchase a registered manufacturing-use product from another firm for formulation into the end-use product.

(ii) Registrants who do not qualify under the formulator's exemption must satisfy the data requirements specified in Table A by submitting data developed with the technical grade of Potassium Bromide.

Rationale: According to the guidelines, ecological effects data must be developed by testing the technical grade of the active ingredient or the manufacturing-use product. The registered use cited in this standard is an indoor use: it does not pose an additional risk to non-target organisms which is not already introduced by the technical grade of Potassium Bromide. Only when the use of an end-use product introduces an additional risk to non-target organisms, which has not been addressed by data developed with the MUP. is additional data required of an end-use product.

1/ Guidelines for Pesticide Assessment, Subdivision E, Hazard Evaluation, Wildlife and Aquatic Organislms, EPA Document 540/9-82-024, October 1982, available from the National Technical Information Service, Springfield, VA, Order No. PB83-1531908.

In the case of the registered product cited in this standard, the registrant uses an unregistered source of the technical grade of Potassium Bromide. Therefore, to reregister this product, the registrant must satisfy the data requirements specified in Table A, as well as those in Table B. For further clarification of this obligation, see pages 1 and 2, Section C(1)(b) on page 7 of this standard, and PR Notice 83-4 previously cited.

4. Environmental Fate Chemistry

No environmental fate chemistry data will be required to re-register the currently registered use. However, if a use such as terrestrial, aquatic, or forest use is proposed for registration, environmental fate chemistry data will be required in accordance with the guidelines 1/.

Rationale: The currently registered use is an indoor use: to sanitize food handling equipment and utensils in food processing establishments. The registered product is used as a very dilute aqueous solution which goes to sewage treatment plants through the municipal sewer systems. Here the chemical is degraded with other components during the treatment process, going from there back to receiving natural bodies of water. Given this, and the registered use being an indoor use, environmental fate chemistry data are not required.

1/ Guidelines for Pesticide Assessment, Subdivision N, Environmental Fate, EPA Document No. 540/9-82-021, Octobrer 1982, available from the National Technical Information Service, Springfield, VA, Order No. PB83-153973.

5. Residue Chemistry

No residue chemistry data will be required to re-register the currently registered use.

Rationale: Residue chemistry data are required to support a petition for a tolerance or an exemption from the requirement of a tolerance when a pesticide use may result in residues in food, feed, tobacco, or other articles used for food or drink for man or animals. For more details on the residue chemistry data requirements the guidelines should be consulted.1/

The registered use for Potassium Bromide is not for direct application on a food crop or food as defined in the guidelines. However, the registered use for the end-use product is as a final sanitizing rinse on food contact surfaces, and food handling equipment and utensils in food processing establishments. As such it is considered an incidental or indirect food additive. Therefore all end-use products proposed for this use must be cleared under the provisions of Section 178.1010 (b) (1) of Title 21 of the Code of Federal Regulations which is administered by the Food and Drug Administration, in accordance with that Agency's requirements.

The registered product cited in this standard has been cleared under Section 178.1010 (b) (1) of 21 CFR, for the registered use.

6. Federal or State Re-entry Levels

It is not necessary to establish federal or state re-entry levels for Potassium Bromide.

Rationale: The registered use is an indoor use with no application to food crops or fields involving exposure to farm workers or field workers.

7. Ground Water Contamination

No data will be required pertaining to ground water contamination.

1/ Guidelines for Pesticide Assessment, Subdivision O, Residue Chemistry, EPA Document No. 540/9-82-023, October 1982, available from the National Technical Information Service, Springfield, VA, Order No. PB83-153981.

Rationale:

The registered use for the registered product is an indoor use: to sanitize food handling equipment and utensils in food processing establishments. As such, the concentration of Potassium Bromide in the use dilution is very small. Potassium Bromide and other chemicals go through municipal sewers, eventually to sewage treatment plants, where these chemicals are further diluted and broken down in the various stages of sewage treatment before finally going back into receiving natural bodies of water. Hence, there is no concern over ground water contamination.

8. Registration of Manufacturing-Use Products

Manufacturing-Use Products containing Potassium Bromide as a sole active ingredient may be registered for sale, distribution, reformulation, and use, subject to the terms and conditions specified in this standard. Registrants must submit or agree to develop additional data, as specified in the tables, in order to maintain existing registrations or to permit new registrations.

Rationale: Under FIFRA, the Agency can not cancel or withhold registration simply because data are missing or inadequate (See Sections 3(c)(2)(B) and 3(c)(7) of the FIFRA). Rather, issuance of this standard provides a mechanism for identifying data needs. The data will be reviewed and evaluated when they are received and the Agency will determine at that time if they will affect the registration of Potassium Bromide.

9. Registration of End-Use Products

In accordance with PR Notice 83-4, the registrant for the end-use product cited in this standard is responsible for satisfying the data requirements for the technical grade of Potassium Bromide (Table A), as well as those of the end-use product (Table B). (See also page 1, §C(1)(b) page 7, and §C(3)(b) page 8 of this standard.)

Rationale: As stated in previous sections of this document, the end-use product cited in this standard must be reregistered in accordance with this standard because the technical grade of Potassium Bromide is not registered as a manufacturing-use product. Furthermore, since the active ingredient present in the end-use product comes from an unregistered source, the registrant of the end-use product does not qualify under the formulator's exemption.

D. CRITERIA FOR REGISTRATION UNDER THIS STANDARD

To be covered by this standard, products must contain Potassium Bromide as an active ingredient, bear required labeling, and conform to the product composition, acute toxicity limits, and use pattern requirements listed in Section E (3) of this chapter.

The applicant for registration or reregistration of products subject to this standard must comply with all terms and conditions described in it, including submission of an up-to-date Confidential Statement of Formula, submission of revised labeling, and commitment to fill data gaps on the schedule specified by the Agency. When circumstances permit, the standard will be supplemented with additional guidance as to data compensation under Sections 3(c)(1)(D) and 3(c)(2)(D) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, 7 U.S.C. 136(c)(1)(D) and 136(c)(2)(D). Registrants should contact the Agency for specific instructions, including updated information on data requirements.

E. ACCEPTABLE RANGES AND LIMITS

1. Product Composition

(a) Manufacturing-Use Products

The technical grade of Potassium Bromide has been defined in this standard as material containing 99% KBr, with only those impurities which are usually considered part of the manufacturing process. If a product of lower purity is proposed as a manufacturing-use product (MUP), the standard must be amended to accommodate such a product. In any case, a manufacturing-use product may contain only those inert ingredients which are either part of the manufacturing process, or are deliberately added to give the product stability or to serve some such other useful purpose, provided however, that all inert ingredients are generally recognized as safe. Each MUP proposed for registration must be fully described with an appropriate certification of limits.

(b) End-Use Products

End-use products proposed for registration under this standard must be substantially similar to the product described on page 4 of this chapter. A product will be considered substantially similar to the registered product if it contains the same active ingredients at approximately the same concentrations, and if it contains inert ingredients generally considered as safe. Furthermore the use proposed for the product must be for the same use as that of the registered product cited in this standard, i.e. as a final sanitizing rinse on food contact surfaces, equipment, and utensils in food processing establishments.

2. Acute Toxicity Limits

(a) Manufacturing-Use Products

The Agency will consider registration of technical grade products and manufacturing-use products containing Potassium Bromide for any proposed acute toxicity categories, provided that the registrant submits enough relevant information, either from the published literature or from other sources, to establish the various acute toxicity categories for the various routes of exposure, thereby permitting the Agency to prescribe appropriate precautionary statements, consistent with Section 162.10 of 40 CFR.

(b) End-Use Products

The only product containing this chemical was registered before 1975, without any supporting acute toxicity data, because at that time the Agency did not routinely require acute toxicity data for all pesticides. To reregister this product or to register similar products the registrant must submit acute toxicity data 1/ (oral LD_{50}, dermal LD_{50}, skin, and eye irritation data) specific to the particular end-use product. This is required to establish the acute toxicity categories for these potential routes of exposure, and thus enable the Agency to prescribe appropriate precautionary statements in accordance with Section 162.10 of 40 CFR. See Table B at the end of this chapter.

1/ Guidelines for Pesticides Assessment, Subdivision F, Hazard Evaluation to Humans and Domestic Animals, Document No. 540/9-82-025, October, 1982, available from the National Technical Information Service, Springfiled, VA, Order No. PB83-1536.

3. Use Patterns

To be registered under this standard, manufacturing-use products containing Potassium Bromide may be labeled for formulation into end-use products only for the following use: as a final sanitizing rinse on food contact surfaces, food handling equipment, and utensils in food processing establishments. All end-use products containing this use must comply with the provisions of Section 178.1010 of Title 21 of the Code of Federal Regulations, which is administered by the Food and Drug Administration.

Furthermore, this is the only use which has been approved for the registered end-use product. To register this chemical for additional uses a registrant must submit an application to amend this standard, and address whatever additional data requirements such uses would incur.

F. REQUIRED LABELING

All manufacturing -use products and end-use products must bear appropriate labeling as specified by Section 162.10 of 40 CFR. For more details on these general labeling requirements see Chapter V of this standard. The following specific comments apply to the labeling for pesticides containing Potassium Bromide.

1. Ingredient Statement

The ingredient statement for Manufacturing-Use Products and End-Use Products must appear on the front part of the label as:

Potassium Bromide ____%

2. Use Patterns

The label for all manufacturing use products must state that they are intended for formulation into end-use products only for the aforementioned use patterns. Labeling must specify sites, which are listed in Section E(3) of this chapter. A limiting factor will be data that support these use patterns. No use may be included on the label where the registrant fails to agree to comply with the data requirements in either Table A or Table B of this standard for that use pattern. Besides this, the label for an MUP must state that each formulator must satisfy EPA's requirements to register each formulated product.

3. Precautionary Statements

(a) Manufacturing-Use Products

(i) Labels for all manufacturing-use products containing Potassium Bromide must bear statements reflecting the product's acute human toxicity as explained previously at Section E(2)(a) of this chapter.

(ii) The following environmental hazard statement must appear on the label of all MUPs, under the required heading as designated below:

ENVIRONMENTAL HAZARDS: Do not discharge effluent containing this active ingredient into lakes, streams, ponds, estuaries, oceans, or public waters unless this product is specifically identified and addressed in an NPDES 1/ permit. Do not discharge effluent containing this product to sewer systems without previously notifying the sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

(iii) Depending on the results of the environmental effects data required to register the MUP the label may require a fish and/or wildlife hazard statement, as specified in Section 162.10(h)(2)(ii) of 40 CFR. For the data requirements see Table A at the end of this chapter.

(b) End-Use Products

The requirement for the environmental hazard statement listed in (a)(ii) above also applies to the label for the end-use product cited in this standard because the use is an industrial use, i.e. as a final sanitizing rinse for food handling equipment and utensils in food processing establishments.

1/ National Pollution Discharge Elimination System

Labeling for each end-use product must bear appropriate precautionary statements specific for the product as formulated. These statements must reflect the acute toxicity categories established by data relevant to the particular product in question, in accordance with Section 162.10 of 40 CFR. For the data requirements see Table B at the end of this chapter.

G. TOLERANCE REASSESSMENT

The registered use for Potassium Bromide does not involve direct application to a food crop or to feed. If a registrant proposes to register the chemical for direct application to a food crop, tobacco, or feed, or to other articles used for food or drink for man or animals, residue chemistry data will be required to support a petition for a tolerance, or an exemption from the requirement of a tolerance.

The registered use is as a final sanitizing rinse for food contact surfaces, food handling equipment and utensils in food processing establishments. As such this use is considered an incidental food additive. Products proposed for this use must be cleared under Section 178.1010 of 21 CFR, which is administered by the Food and Drug Administration. This use has been addressed at Section C(5) of this standard.

H. EFFICACY DATA REQUIREMENTS

Section 162.18-2(d)(2) of 40 CFR requires that "efficacy data specific to each product that bears a claim to control organisms that may pose a threat to human health, either directly or through transmittal of disease" must be submitted to support the registration of such a product. Each antimicrobial product intended to control microorganisms infectious to man in any area where these microorganisms may present a health hazard falls under the requirement of this section. Microbiological efficacy data are product specific; data for one product can not be used to support registration of another product unless the two products are identical. Even then confirmatory data is required to register a product relying on data developed with another product.

The specific data requirements for end-use products intended to provide health related benefits can be found in the guidelines for product performance 1/. Besides satisfying these requirements each end-use product proposed for use as a final sanitizing rinse on food contact surfaces, food handling equipment, and eating utensils in food processing establishments, must comply with FDA's regulations at Section 178.1010 of 21 CFR.

In the case of the only registered product referred to in this standard, the efficacy data requirements have been satisfied.

1/ Pesticide Assessment Guidelines, Subdivision G, Product Performance, EPA Document No. 540/9-82-026, November 1982, available from the National Technical Information Service, Springfield, VA, Order No. PB83-153924.

III. REQUIREMENT FOR SUBMISSION OF GENERIC DATA

A. This portion of the guidance document is a Notice issued under the authority of FIFRA Section 3(c)(2)(B) and describes, in table format, the data required for maintaining the registrability of each product. Additionally, a bibliography (Appendix III-1) is included that identifies that data considered as part of the data base supporting this standard. EPA has determined that additional generic data described in this Notice must be submitted to EPA for evaluation in order to maintain in effect the registration(s) of your product(s) identified as an attachment to the cover letter accompanying this guidance document. As required by FIFRA Section 3(c)(2)(B), you are required to take appropriate steps to comply with this Notice.

EPA may suspend the registration of each of those products unless, within the specified time, you have informed EPA how you will satisfy the requirements of this Notice. Any such suspension will remain in effect until you have complied with the terms of this Notice.

B. What Generic Data 1/ Must Be Submitted. You may ascertain which generic data you must submit by consulting Table A at the end of this chapter. That table shows all the generic data needed to evaluate the continued registrability of all products, and the dates by which the data must be submitted. The required data must be submitted and any necessary studies must be conducted in accordance with EPA-approved protocols, the Pesticide Registration Guidelines 2/, or data collected under the approved protocols of the Organization for Economic Cooperation and Development (OECD). If you wish not to develop data which are necessary to support the registration or reregistration of certain uses appearing in your labeling, you may delete those uses at the time you submit your revised labeling.

Also for certain kinds of testing (generally ecological effects), EPA requires the test substance to be a "typical formulation," and in those cases EPA needs data of that

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1/ Generic data pertain to the properties or effects of a particular ingredient, and thus are relevant to an evaluation of the risks of all products containing that ingredient (or all such products having a certain use pattern), regardless of any such product's unique composition or use. Product-specific data relate only to the properties or effects of a product with a particular composition (or a group of products with closely similar composition).

2/ The Pesticide Registration Guidelines were reproposed on November 24, 1982 in 47 Federal Register 53192.

type for each major formulation category (e.g., emulsifiable concentrates, wettable powders, granulars, etc.) These are classified as generic data and when needed are specified in Table A. EPA may possess data on certain "typical formulations" but not others. Note: The "typical formulation" data should not be confused with product-specific data (Table B) which are required on each formulation. Product-specific data are further explained in Chapter IV of this document.

C. Options Available for Complying With Requirements to Submit Data

Within 90 days of your receipt of this Notice you must submit to EPA a completed copy of the form entitled "FIFRA Section 3(c)(2)(B) Summary Sheet" [EPA Form 8580-1, Appendix III-2] for each of your products. On that form you must state which of the following methods you will use to comply with the requirements of this Notice:

1. (a) Notify EPA that you will submit the data, and

   (b) either submit the existing data you believe will satisfy the requirement, or state that you will generate the data by conducting testing. If the test procedures you will use deviate from (or are not specified in) the Registration Guidelines or protocols contained in the Reports of Expert Groups to the Chemicals Group, Organization for Economic Cooperation and Development (OECD) Chemicals Testing Programme, you must enclose the protocols you will use.

2. Notify EPA that you have entered into an agreement with one or more other registrants to jointly develop (or share in the cost of developing) the data. If you elect this option, you must notify EPA which registrant(s) are parties to the agreement.

3. File with EPA a completed "Certification of Attempt to Enter Into an Agreement With Other Registrants for Development of Data" (EPA Form 8580-6, Appendix III-3)*/

4. Request that EPA amend your registration by deleting the uses for which the data are needed. (This option is not available to applicants for new products.)

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*/ FIFRA Section 3(c)(2)(B) authorizes joint development of data by two or more registrants, and provides a mechanism by which parties can obtain an arbitrator's decision if they agree to jointly develop data but fail to agree on all the terms of the agreement. The statute does not compel any registrant to agree to develop data jointly.

(Footnote continued at bottom of next page)

5. Request voluntary cancellation of the registration(s) of your products for which the data are needed. (This option is not available to applicants for new products.)

D. Procedures for Requesting Changes in Testing Methodology and Extensions of Time

EPA recognizes that you may disagree with our conclusions regarding the appropriate ways to develop the required data or how quickly the data must be submitted. If the test procedures you plan to use deviate from (or are not specified in) the registration guidelines or protocols contained in the reports of the Expert Groups to the Chemical Groups, Organization for Economic Cooperation and Development (OECD) Chemicals Testing Programme, you must submit the protocol for Agency review prior to the initiation of the test.

If you think that you will need more time to generate the required data than is allowed by EPA's schedule, you may submit a request for an extension of time. The extension request must be submitted in writing to the Product Manager. The extension request should state the reasons why you conclude that an extension is appropriate. While EPA considers your request, you must strive to meet the deadline for submitting the required data.

(Footnote continued from previous page)

In EPA's opinion, joint data development by all registrants who are subject to the requirements to submit a pertinent item of data or a cost-sharing agreement among all such registrants is clearly in the public interest. Duplication of testing could increase costs, tie up testing facilities, and subject an unnecessarily large number of animals to testing.

As noted earlier, EPA has discretion not to suspend the registration of a product when a registrant fails to submit data required under FIFRA Section 3(c)(2)(B). EPA has concluded that it is appropriate to exercise its discretion not to suspend in ways which will discourage duplicative testing. Accordingly, if (1) a registrant has informed us of his intent to develop and submit data required by this Notice; and (2) a second registrant informs EPA that it has made a bona fide offer to the first registrant to share in the expenses of the testing [on terms to be agreed upon or determined by arbitration under FIFRA Section 3(c)(2)(B)(iii)]; and (3) the first registrant has declined to agree to enter into a cost-sharing agreement, EPA will not suspend the second firm's registration. While the first firm is not required to agree to jointly develop data, EPA is not required to force the second firm to engage in economically inefficient duplicative testing in order to maintain its registration.

TABLE A
GENERIC DATA REQUIREMENTS FOR POTASSIUM BROMIDE (99% purity or higher)

Data Requirement	Composition (Unregistered Product) 1/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)? 2/ 2/
§158.120 Product Chemistry				
Product Identity:				
61-1 - Identity of Ingredients	TGAI	Totally	GS 0342-001 GS 0342-002 MRID 00019750 MRID 00007445	No
61-2 - Statement of Composition	TGAI	Partially	GS 0342-002 Standard Ref's	Yes -
61-3 - Discussion of Formation of Ingredients	TGAI	N/A	-	
Analysis and Certification of Product Ingredients				
62-1 - Preliminary Analysis	TGAI	N/A	-	-
62-2 - Certification of Limits	TGAI	N/A	-	-
62-3 - Analytical Methods for Enforcement of Limits	TGAI	N/A	-	-
Physical and Chemical Characteristics				
63-2 - Color	TGAI	Totally	Standard Ref's	No
63-3 - Physical State	TGAI	Totally	Standard Ref's	No
63-4 - Odor	TGAI	Totally	Standard Ref's	No
63-5 - Melting Point	TGAI	Totally	Standard Ref's	No
63-6 - Boiling Point	TGAI	Totally	Standard Ref's	No
63-7 - Density, Bulk Density, or Specific Gravity	TGAI	Totally	Standard Ref's	No

TABLE A
GENERIC DATA REQUIREMENTS FOR POTASSIUM BROMIDE (99% purity or higher)

Data Requirement	Composition (Unregistered Product) 1/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?2/ 2/
§158.120 Product Chemistry (continued)				
63- 8 - Solubility	TGAI	Totally	Standard Ref's	No
63-12 - pH	TGAI	Totally	Standard Ref's	No
63-13 - Stability	TGAI	Totally	Standard Ref's	No

1/ Composition: TGAI = Technical grade of the active ingredient; PAI = Pure active ingredient; Choice = Choice of several test substances determined on a case-by-case basis.
2/ Data must be submitted no later than _____.

TABLE A
GENERIC DATA REQUIREMENTS FOR POTASSIUM BROMIDE (99% purity or higher)

Data Requirement	Composition 1/	Use Patterns 2/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)? 3/
§158.135 Toxicology					
ACUTE TESTING:					
81-1 - Oral LD_{50} - Rat	TGAI	I	No	-	Yes 4/
81-2 - Dermal LD_{50} - Rabbit	TGAI	I	No	-	Yes 4/
81-3 - Inhalation LC_{50} - Rat	TGAI	I	No	-	Yes 4/
81-7 - Delayed Neurotoxicity - Hen	TGAI	I	No	-	Yes 4/
SUBCHRONIC TESTING:					
82-1 - 90-Day Feeding - Rodent, Non-rodent	TGAI	I	N/A	-	-
82-2 - 21-Day Dermal - Rabbit	TGAI	I	N/A	-	-
82-3 - 90-Day Dermal - Rabbit	TGAI	I	N/A	-	-
82-4 - 90-Day Inhalation - Rat	TGAI	I	N/A	-	-
82-5 - 90-Day Neurotoxicity- Hen/Mammal	TGAI	I	N/A	-	-

TABLE A
GENERIC DATA REQUIREMENTS FOR POTASSIUM BROMIDE (99% purity or higher)

§158.135 Toxicology
(continued)

1/ Composition: PAI = Pure active ingredient; PAIRA = Pure active ingredient, radiolabelled; Choice = Choice of several test substances determined on a case-by-case basis.
2/ The use patterns are coded as follows: A=Terrestrial, Food Crop; B=Terrestrial, Non-Food; C=Aqautic, Food Crop; D=Aquatic, Non-Food; E=Greenhouse, Food Crop; F=Greenhouse, Non-Food; G=Forestry; H=Domestic Outdoor; I=Indoor.
3/ Data must be submitted no later than _____.
4/ These data apply to the Technical Grade of Potassium Bromide (99% purity or higher). To date it has not been registered as a Manufacturing Use Product for formulation into pesticides. If a registrant proposes to register this product as an MUP pesticide, it is very likely that information addressing these requirements may be obtained from the published literature. Otherwise the registrant would have to develop these data to establish the various acute toxicity categories for the TGAI or other MUP products, so that appropriate precautionary labeling can be prescribed in accordance with Section 162.10 of 40 CFR.

TABLE A
GENERIC DATA REQUIREMENTS FOR POTASSIUM BROMIDE (99% purity or higher)

Data Requirement	Composition 1/	Use Pattern 2/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)? 3/
§158.145 Wildlife and Aquatic Organisms					
AVIAN AND MAMMALIAN TESTING					
71-1 - Avian Oral LD_{50}	TGAI	I	No	-	Yes 4/
71-2 - Avian Dietary LC_{50} *	TGAI	I	No	-	Yes 4/
71-3 - Wild Mammal Toxicity	TGAI	-	-	-	-
71-4 - Avian Reproduction	TGAI	-	-	-	-
71-5 - Simulated and Actual Field Testing - Mammals and Birds	TEP	-	-	-	-
AQUATIC ORGANISM TESTING					
72-1 - Freshwater Fish LC_{50} **	TGAI	I	No	-	Yes 4/
72-2 - Acute LC_{50} Freshwater Invertebrates (48 hours)	TGAI	I	No	-	Yes 4/
72-3 - Acute LC_{50} Estuarine and Marine Organisms	TGAI	-	-	-	-
72-4 - Fish Early Life Stage and Aquatic Invertebrate Life-Cycle	TGAI	-	-	-	-

* one specie ; ** one species bluegill or rainbow trout

TABLE A
GENERIC DATA REQUIREMENTS FOR POTASSIUM BROMIDE (99% purity or higher)

§158.145 Wildlife and Aquatic Organisms
(continued)

1/ Composition: TGAI = Technical grade of the active ingredient; PAI = pure active ingredient; TEP = Typical end-use product;
2/ The use patterns are coded as follows: A=Terrestrial, Food Crop; B=Terrestrial, Non-Food Crop; C=Aquatic, Food Crop; D=Aquatic, Non-Food; E=Greenhouse, Food Crop; F=Greenhouse, Non-Food; G=Forestry; H=Domestic Outdoor; I=Indoor.
3/ Data must be submitted no later than _____.
4/ These tests must be developed with the Technical Grade of Potassium Bromide (99% purity or higher) to support registration as a Manufacturing Use pesticide for the indoor uses specified in this standard. If the uses are expanded to include other than indoor uses more data will be required.

IV. REQUIREMENT FOR SUBMISSION OF PRODUCT-SPECIFIC DATA

Note: This chapter applies only to manufacturing-use products, not end-use products.

A necessary first step in determining which statements must appear on your product's label is the completion and submission to EPA of product-specific data* listed on the form entitled "Product Specific Data Report" (EPA Form 8580-4, Appendix IV-1) to fill "gaps" identified by EPA concerning your product. Under the authority of FIFRA Section 3(c)(2)(B), EPA has determined that you must submit these data to EPA in order to register or reregister your product(s). All of these data must be submitted not later than six months after you receive this guidance document.

"Product-Specific Data Requirements for Manufacturing-Use Products" appearing in Table B permit you to determine which product-specific data you must submit. This can be done by examining the entries in the column of those tables entitled "Must Data Be Submitted Under §3(c)(2)(B)."

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*/ Product specific data pertains to data that support the formulation which is marketed; it usually includes product chemistry data and acute toxicology data.

TABLE B
PRODUCT SPECIFIC DATA REQUIREMENTS FOR END USE PRODUCT SAF SOL: EPA REG NO: 875-42 3/

Data Requirement	Composition 1/ 4/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)? 2/
§158.120 Product Chemistry				
Product Identity				
61-1 - Identity of Ingredients	EP	Totally	EPA Reg No 875-42	No
61-2 - Statement of Composition	EP	Partially 5/	EPA Reg No 875-42	Yes
61-3 - Discussion of Formation of Ingredients	EP	Partially 5/	EPA Reg No 875-42	Yes
Analysis and Certification of Product Ingredients:				
62-1 - Preliminary Analysis	EP	N/A	-	-
62-2 - Certification of Limits	EP	Partially	EPA Reg No 875-42	Yes
62-3 - Analytical Methods for Enforcement of Limits	EP	Totally	Standard Ref's	No
Physical and Chemical Characteristics				
63-2 - Color	EP	Totally	Standard Ref's	No
63-3 - Physical State	EP	Totally	EPA Reg No 875-42	No
63-4 - Odor	EP	Totally	Standard Ref's	No
63-7 - Density, bulk density, or specific gravity	EP	Totally	EPA Reg No 875-42	No

TABLE B

PRODUCT SPECIFIC DATA REQUIREMENTS FOR END USE PRODUCT SAF SOL®: EPA REG NO: 875-42 3/

Data Requirement	Composition 1/ 4/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)? 2/6/
§158.120 Product Chemistry (continued)				
63-12 - pH	EP	Totally	00007442	No
63-14 - Oxidizing or reducing action	EP	Totally	EPA Reg No 875-42	No
63-16 - Explodability	EP	Partially 4/	EPA Reg No 875-42	Yes
63-17 - Storage Stability	EP	Totally	00007442	No
63-20 - Corrosion Characteristics	EP	Totally	00007442	No

1/ Composition: MP = Manufacturing-use product; Choice = Choice of several test substances determined on a case-by-case basis.

2/ Data must be submitted no later than _____.

3/ In view of its commercial availability as an engraving and photographic processing chemical, there is no requirement under the FIFRA (or need) to register technical potassium bromide for manufacturing use.

4/ The active ingredients of SAF SOL® Brand Sanitizer are 2.00% potassium bromide, 3.25% sodium hypochlorite and 89.75% trisodium phosphate (as a hydrate salt). Since anhydrous hypochlorite may be explosive, information is needed concerning the hydrated form of sodium hypochlorite used in formulating SAF SOL® Brand Sanitizer.

5/ For the technical potassium bromide used in formulating SAF SOL®, the Diversey Corporation is required to submit the detailed composition data available from their supplier(s). This composition data should include the amounts of lead and other heavy metal impurities. For the marketed product, information is needed concerning the quality control procedures and a discussion of impurities that are expected to form during the commercial life of the product.

6/ These chemistry data requirements apply for the reregistration of SAF SOL® (EPA Reg No 875-42) under this Standard. They will not support registration of another end use product unless the product in question is identical and then only with the permission from the owner to cite it. A registrant of any other end use product containing potassium bromide would be required to address all of the applicable product chemistry requirements specified in section 158.120 of 40 CFR.

TABLE B
PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING POTASSIUM BROMIDE

Data Requirement	Composition 1/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)? 2/
§158.135 Toxicology				
ACUTE TESTING				
81-1 - Oral LD_{50} - Rat	MP	No	-	Yes
81-2 - Dermal LD_{50} - Rabbit	MP	No	-	Yes
81-3 - Inhalation LC_{50} - Rat	MP	N/A	-	-
81-4 - Primary Eye Irritation - Rabbit	MP	No	-	Yes
81-5 - Primary Dermal Irritation - Rabbit	MP	No	-	Yes
81-6 - Dermal Sensitization - Guinea Pig	MP	No	-	No

1/ Composition: MP = Manufacturing-use product.
2/ data must be submitted no later than _____.

V. SUBMISSION OF REVISED LABELING AND PACKAGING INFORMATION

Note: This section applies to manufacturing-use products, and end-use products.

The Agency requires applicants for registration or reregistration to ensure that each label (1) contains accurate, complete, and sufficient instructions and precautions, reflecting the results of data concerning the product and its ingredients, and (2) incorporates labeling format and terminology which are sufficiently standardized to avoid user confusion.

As part of your application, you will be required to submit draft labeling consistent with: applicable product-specific data; the precautionary statements and use directions; and the regulations concerning classification [40 CFR §162.11(c)], packaging [40 CFR §162.16], and labeling [40 CFR §162.10, Appendix V-1 and V-2], as indicated by the following paragraphs of this section of the guidance document.

You will be informed later when you must submit the revised labeling set forth in this guidance package.

A. Label Contents

40 CFR §162.10 (Appendix V-1) requires that certain specific labeling statements must appear at certain locations on the label. This is referred to as format labeling. Specific label items listed below are keyed to Tables D, E, and F (Appendix VI-2).

Item 1. PRODUCT NAME - The name, brand, or trademark is required to be located on the front panel, preferably centered in the upper part of the panel. The name of a product will not be accepted if it is false or misleading. See Appendix V-1. [40 CFR §162.10(b)]

Item 2. COMPANY NAME AND ADDRESS - The name and address of the registrant or distributor is required on the label. The name and address should preferably be located at the bottom of the front panel or at the end of the label text. See Appendix V-1. [40 CFR §162.10(c)]

Item 3. NET CONTENTS - A net content statement is required on all labels. The preferred location is the bottom of the front panel immediately above the company name and address, or at the end of the label text. The net contents must be stated in terms of weight, expressed as avoirdupois pounds

and ounces, and stated in terms of the largest suitable unit, i.e., "1 pound 10 ounces" rather than "26 ounces." In addition to the required units specified, net contents may be expressed in metric units. See Appendix V-1. [40 CFR §162.10(d)]

Item 4. EPA REGISTRATION NUMBER - The registration number assigned to the pesticide product must appear on the label, preceded by the phrase "EPA Registration No.," or "EPA Reg. No." The registration number must be set in type of a size and style similar to other print on that part of the label on which it appears and must run parallel to it. The registration number and the required identifying phrase must not appear in such a manner as to suggest or imply recommendation or endorsement of the product by the Agency. See Appendix V-1. [40 CFR §162.10(e)]

Item 5. EPA ESTABLISHMENT NUMBER - The EPA establishment number, preceded by the phrase "EPA Est." is the final establishment at which the product was produced, and may appear in any suitable location on the label or immediate container. It must also appear on the wrapper or outside container of the package if the EPA establishment registration number on the immediate container cannot be clearly read through such wrapper or container. See Appendix V-1. [40 CFR §162.10(f)]

Item 6. INGREDIENT STATEMENT - An ingredient statement is required on the front panel and must contain the name and percentage by weight of each active ingredient and the total percentage by weight of all inert ingredients. The preferred location is immediately below the product name. The ingredient statement must run parallel with, and be clearly distinguished from, other text on the panel. It must not be placed in the body of other text. See Appendix V-1. [40 CFR 162.10(g)]

Item 6A. POUNDS PER GALLON STATEMENT - For liquid agricultural formulations, the pounds per gallon of active ingredient must be indicated on the label.

Item 7. FRONT LABEL PRECAUTIONARY STATEMENTS - All labels are required to have precautionary statements grouped together on the front panel, preferably within a block outline. The table below shows the minimum type size requirements on various size labels, as set forth in the Regulations.

Size of Label on Front Panel in Square Inches	Signal Word as Required Minimum Type Size All Capitals	"Keep Out of Reach of Children" as Required
5 and under	6 point	6 point
above 5 to 10	10 point	6 point
above 10 to 15	12 point	8 point
above 15 to 30	14 point	10 point
over 30	18 point	12 point

Item 7A. CHILD HAZARD WARNING STATEMENT - All labels are required to have the statement "Keep Out of Reach of Children" located on the front panel above the signal word except where contact with children during distribution or use is unlikely. See Appendix V-1. [40 CFR §162.10(h)(1)(ii)]

Item 7B. SIGNAL WORD - The signal word (Caution, Warning, or Danger) is required on the front panel immediately below the child hazard warning statement. See Appendix V-1. [40 CFR §162.10 (h)(1)(i)]

Item 7C. SKULL & CROSSBONES AND WORD "POISON" - On products assigned a toxicity Category I on the basis of oral, inhalation, or dermal toxicity, the word "Poison" shall appear on the label in red on a background of distinctly contrasting color and the skull and crossbones shall appear in immediate proximity to the word poison. See Appendix V-1. [40 CFR §162.10(h)(1)(i)]

Item 7D. STATEMENT OF PRACTICAL TREATMENT - A statement of practical treatment (first aid or other) shall appear on the label of pesticide products in toxicity Categories I, II, and III. See Appendix V-1. [40 CFR §162.10(h)(1)(iii)].

Item 7E. REFERRAL STATEMENT - The statement "See Side (or Back) Panel for Additional Precautionary Statements" is required on the front panel for all products, unless all required precautionary statements appear on the front panel. See Appendix V-1. [40 CFR §162.10(h)(1)(iii)].

Item 8. SIDE/BACK PANEL PRECAUTIONARY LABELING - The precautionary statements as listed below must appear together on the label under the heading "PRECAUTIONARY STATEMENTS." The preferred location is at the top of the side or back panel preceding the directions for use, and it is preferred that these statements be surrounded by a block outline. Each of the three hazard warning statements must be headed by the appropriate hazard title. See Appendix V-1. [40 CFR §162.10 (h)(2)]

Item 8A. HAZARD TO HUMANS AND DOMESTIC ANIMALS - Where a hazard exists to humans or domestic animals, precautionary statements are required indicating the particular hazard, the route(s) of exposure and the precautions taken to avoid accident, injury or damage. See Appendix V-1. [40 CFR §162.10 (h)(2)(i)]

Item 8B. ENVIRONMENTAL HAZARD - Where a hazard exists to non-target organisms excluding humans and domestic animals, precautionary statements are required stating the nature of the hazard and the appropriate precautions to avoid potential accident, injury, or damage. See Appendix V-1. [40 CFR §162.10(h)(2)(ii)]

Item 8C. PHYSICAL OR CHEMICAL HAZARD

1. Flammability statement. Precautionary statements relating to flammability of a product are required to appear on the label if it meets the criteria in Appendix V-3. The requirement is based on the results of the flashpoint determinations and flame extension tests required to be submitted for all products. These statements are to be located in the side/back panel precautionary statements section, preceded by the heading "Physical/Chemical Hazards." Note that no signal word is used in conjunction with the flammability statements.

2. Criteria for declaration of non-flammability. The following criteria will be used to determine if a product is non-flammable:

   a. A "non-flammable gas" is a gas (or mixture of gases) that will not ignite when a lighted match is placed against the open cylinder valve.

   b. A "non-flammable liquid" is one having a flashpoint greater than 350°F (177°C) as determined by the method specified in 40 CFR §163.61-8(c)(13)(ii) of Subpart D.

   c. A "non-flammable aerosol" is one which meets the following criteria:

      i. The flame extension is zero inches, using the method specified in 40 CFR §163.61-8(c)(13)(ii);

      ii. There is no flash back; and

      iii. The flashpoint of the non-volatile liquid component is greater than 350°F (177°C), determined by the method specified in 40 CFR §163.61-8(c)(13)(i).

3. Declaration of non-flammability. Products which meet the criteria for non-flammability specified above may bear the notation "non-flammable" or "nonflammable (gas, liquid, etc.)" on the label.

   It may appear as a substatement to the ingredients statement, or on a back or side panel, but shall not be highlighted or emphasized (as with an inordinately large type size) in any way that may detract from precaution.

4. Other physical/chemical hazard statements. When chemistry data submitted in accordance with 40 CFR §163.61-10(i) demonstrate hazards of a physical or chemical nature other than flammability, appropriate statements of hazard will be prescribed. Such statements may address hazards of explosivity, oxidizing or reducing capability, or mixing with other substances to produce toxic fumes.

Item 9. MISUSE STATEMENT - The following statement is required on your label: "It is a violation of Federal law to use this product in a manner inconsistent with its labeling." See Appendix V-1. [40 CFR §162.10(l)(2)(ii)]

Item 10A. STORAGE AND DISPOSAL BLOCK - All labels are required to bear storage and disposal statements. These statements are developed for specific containers, sizes, and chemical content. Make certain that the statement you use pertains specifically to your product. These instructions must be grouped and appear under the heading "Storage and Disposal" in the directions for use. This heading must be set in the same type sizes as required for the child hazard warning. Refer to Appendix V-5 for the latest specific storage and disposal product label statements.

Item 10B. DIRECTIONS FOR USE - Directions for use must be stated in terms which can be easily read and understood by the average person likely to use or to supervise the use of the pesticide. When followed, directions must be adequate to protect the public from fraud and from personal injury and to prevent unreasonable adverse effects on the environment. See Appendix V-1. [40 CFR §162.10]

B. Collateral Information

Bulletins, leaflets, circulars, brochures, data sheets, flyers, and other graphic printed matter which is referred to on the label or which is to accompany the product are termed collateral labeling. Such labeling may not bear claims or representations that differ in substance from those accepted in connection with registration of the product. It should be made part of the response to this notice and submitted for review.

VI. INSTRUCTIONS FOR SUBMISSION

All applications prepared in response to this Notice should be addressed as follows:

[Product Manager]
Phone No. (703)_____
Registration Division (TS-767)
Office of Pesticide Programs
Environmental Protection Agency
Washington, D.C. 20460

A. For each manufacturing-use product for which continued registration is desired:

1. Within 90 days from receipt of this document, you must submit the "FIFRA Section 3(c)(2)(B) Summary Sheet" EPA Form 8580-1. Refer to Appendix III-2 with appropriate attachments.

2. Within 6 months from receipt of this document registrants must submit:

   a. Confidential Statement of Formula, EPA Form 8570-4.

   b. Product Specific Data Report, EPA Form 8580-4 (Appendix IV-1).

   c. Two copies of any required product-specific data.

3. Within the time set forth in Table A, all generic data must be submitted by the affected registrant(s).

Note: If for any reason any required test is delayed or aborted so that meeting the agreed submission time will be delayed, notify the Product Manager listed above.

B. For each affected product for which continued registration is desired, within 90 days from receipt of this document submit the "FIFRA Section 3(c)(2)(B) Summary Sheet" (EPA Form 8580-1, Appendix III-2) with appropriate attachments.

C. You will be informed at a later date when you must submit your Application for Amended Pesticide Registration (EPA Form 8570-1) and the revised labeling set forth in this guidance package.

OFFICE OF PESTICIDE PROGRAMS
Registration Standard Bibliography

Citations Considered to be Part of the Data Base Supporting Registrations Under the Standard

MRID 00007445 Diversey Corporation (1957) Presence of Hypobromite in SAF-SOL (PX-829) Solution. (Unpublished study received Nov. 6, 1957 under 875-42; CDL: 022231-A)

MRID 00007442 Diversey Corporation (1962?) SAF-SOL as a sanitizer for use in Food Processing Plants. (Unpublished study received Feb 18, 1963 under 875-42; CDL: 022229-A)

MRID 00019750 A.; Carrera, R.T.; Kelley, M.J. (1961) Information on conversion rate of Bromide to Hypobromite in solutions of Diversey PX-1216. (Unpublished study received Oct. 5, 1961 under 875-45; submitted by Diversey Chemical Co., Des Plains, Ill., CDL: 231083-F)

GS-0342-001 Smith, M.K. (1983) Qualitative Use. Assessment Document for Potassium Bromide

GS-0342-002 EPA (1983) The Calcium and Sodium Hypochlorite Salts, Pesticide Registration Standard Part I (Unpublished)

OMB Approval No. 2000-0468 (Expires 12-31-8.

FIFRA SECTION 3(C)(2)(B) SUMMARY SHEET

EPA REGISTRATION NO. (38)

PRODUCT NAME

APPLICANT'S NAME

DATE GUIDANCE DOCUMENT ISSUED

With respect to the requirement to submit "generic" data imposed by the FIFRA section 3(C)(2)(B) notice contained in the referenced Guidance Document, I am responding in the following manner:

☐ 1. I will submit data in a timely manner to satisfy the following requirements. If the test procedures I will use deviate from (or are not specified in) the Registration Guidelines or the Protocols contained in the Reports of Expert Groups to the Chemicals Group, OECD Chemicals Testing Programme, I enclose the protocols that I will use:

☐ 2. I have entered into an agreement with one or more other registrants under FIFRA section 3(C)(2)(B)(ii) to satisfy the following data requirements. The tests, and any required protocols, will be submitted to EPA by:

NAME OF OTHER REGISTRANT

☐ 3. I enclose a completed "Certification of Attempt to Enter Into an Agreement with Other Registrants for Development of Data" with respect to the following data requirements:

☐ 4. I request that you amend my registration by deleting the following uses (this option is not available to applicants for new products):

☐ 5. I request voluntary cancellation of the registration of this product. (This option is not available to applicants for new products.)

REGISTRANT'S AUTHORIZED REPRESENTATIVE	SIGNATURE	DATE

OMB Approval No. 2000-0468 (Expires: 12-31-8

CERTIFICATION OF ATTEMPT TO ENTER INTO AN AGREEMENT WITH OTHER REGISTRANTS FOR DEVELOPMENT OF DATA

(To qualify, certify ALL four items)

1. I am duly authorized to represent the following firm(s) who are subject to the requirements of a Notice under FIFRA Section 3(c)(2)(B) contained in a Guidance Document to submit data concerning the active ingredient:

GUIDANCE DOCUMENT DATE

ACTIVE INGREDIENT

NAME OF FIRM	EPA COMPANY NUMBER

(This firm or group of firms is referred to below as "my firm".)

2. My firm is willing to develop and submit the data as required by that Notice, if necessary. However, my firm would prefer to ente into an agreement with one or more other registrants to develop jointly, or to share in the cost of developing, the following require items or data:

3. My firm has offered in writing to enter into such an agreement. Copies of the offers are attached. That offer was irrevocable and included an offer to b bound by an arbitration decision under FIFRA Section 3(c)(2)(B)(iii) if final agreement on all terms could not be reached otherwise. This offer was mad to the following firm(s) on the following date(s):

NAME OF FIRM	DATE OF OFFER

However, none of those firm(s) accepted my offer.

4. My firm requests that EPA not suspend the registration(s) of my firm's product(s), if any of the firms named in paragraph (3) abov have agreed to submit the data listed in paragraph (2) above in accordance with the Notice. I understand EPA will promptly inform me whether my firm must submit data to avoid suspension of its registration(s) under FIFRA Section 3(c)(2)(B). (This statemen does not apply to applicants for new products.) I give EPA permission to disclose this statement upon request.

TYPED NAME	SIGNATURE	DATE

Appendix IV-1

PRODUCT SPECIFIC DATA REPORT

EPA Registration No._____ Guidance Document for_____

Date_____

Registration Guideline No.	Name of Test	Test not required for my product listed above (check below)	I am complying with data requirements by		(For EPA Use Only) Accession Numbers Assigned
			Citing MRID#	Submitting Data (Attached)	
§158.20 PRODUCT CHEMISTRY					
61-1	Identity of ingredients				
61-2	Statement of composition				
61-3	Discussion of formation of ingredients				
62-1	Preliminary analysis				
62-2	Certification of limits				
62-3	Analytical methods for enforcement limits				
63-2	Color				
63-3	Physical state				
63-4	Odor				
63-5	Melting point				
63-6	Boiling point				
63-7	Density, bulk-density, or specific gravity				
63-8	Solubility				
63-9	Vapor pressure				
63-10	Dissociation constant				
63-11	Octanol/water partition coefficient				
63-12	pH				
63-13	Stability				
63-14	Oxidizing/reducing reaction				
63-15	Flammability				
63-16	Explodability				
63-17	Storage stability				
63-18	Viscosity				
63-19	Miscibility				
63-20	Corrosion characteristics				
63-21	Dielectric breakdown voltage				
§158.135 TOXICOLOGY					
81-1	Acute oral LD-50, rat				
81-2	Acute dermal LD-50				
81-3	Acute inhalation, LC-50 rat				
81-4	Primary eye irritation, rabbit				
81-5	Primary dermal irritation				
81-6	Dermal sensitization				

§ 162.10 Labeling requirements.

(a) *General*—(1) *Contents of the label.* Every pesticide products shall bear a label containing the information specified by the Act and the regulations in this Part. The contents of a label must show clearly and prominently the following:

(i) The name, brand, or trademark under which the product is sold as prescribed in paragraph (b) of this section;

(ii) The name and address of the producer, registrant, or person for whom produced as prescribed in paragraph (c) of this section;

(iii) The net contents as prescribed in paragraph (d) of this section;

(iv) The product registration number as prescribed in paragraph (e) of this section;

(v) The producing establishment number as prescribed in paragraph (f) of this section;

(vi) An ingredient statement as prescribed in paragraph (g) of this section;

(vii) Warning or precautionary statements as prescribed in paragraph (h) of this section;

(viii) The directions for use as prescribed in paragraph (i) of this section; and

(ix) The use classification(s) as prescribed in paragraph (j) of this section.

(2) *Prominence and legibility.* (i) All words, statements, graphic representations, designs or other information required on the labeling by the Act or the regulations in this part must be clearly legible to a person with normal vision, and must be placed with such conspicuousness (as compared with other words, statements, designs, or graphic matter on the labeling) and expressed in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

(ii) All required label text must:

(A) Be set in 6-point or larger type;

(B) Appear on a clear contrasting background; and

(C) Not be obscured or crowded.

(3) *Language to be used.* All required label or labeling text shall appear in the English language. However, the Agency may require or the applicant may propose additional text in other languages as is considered necessary to protect the public. When additional text in another language is necessary, all labeling requirements will be applied equally to both the English and other-language versions of the labeling.

(4) *Placement of Label*—(i) *General.* The label shall appear on or be securely attached to the immediate container of the pesticide product. For purposes of this Section, and the misbranding provisions of the Act, "securely attached" shall mean that a label can reasonably be expected to remain affixed during the foreseeable conditions and period of use. If the immediate container is enclosed within a wrapper or outside container through which the label cannot be clearly read, the label must also be securely attached to such outside wrapper or container, if it is a part of the package as customarily distributed or sold.

(ii) *Tank cars and other bulk containers*—(A) *Transportation.* While a pesticide product is in transit, the appropriate provisions of 49 CFR Parts 170-189, concerning the transportation of hazardous materials, and specifically those provisions concerning the labeling, marking and placarding of hazardous materials and the vehicles carrying them, define the basic Federal requirements. In addition, when any registered pesticide product is transported in a tank car, tank truck or other mobile or portable bulk container, a copy of the accepted label must be attached to the shipping papers, and left with the consignee at the time of delivery.

(B) *Storage.* When pesticide products are stored in bulk containers, whether mobile or stationary, which remain in the custody of the user, a copy of the label of labeling, including all appropriate directions for use, shall be securely attached to the container in the immediate vicinity of the discharge control valve.

(5) *False or misleading statements.* Pursuant to section 2(q)(1)(A) of the Act, a pesticide or a device declared subject to the Act pursuant to § 162.15, is misbranded if its labeling is false or misleading in any particular including both pesticidal and non-pesticidal claims. Examples of statements or representations in the labeling which constitute misbranding include:

(i) A false or misleading statement concerning the composition of the product;

(ii) A false or misleading statement concerning the effectiveness of the product as a pesticide or device;

(iii) A false or misleading statement about the value of the product for purposes other than as a pesticide or device;

(iv) A false or misleading comparison with other pesticides or devices;

(v) Any statement directly or indirectly implying that the pesticide or device is recommended or endorsed by any agency of the Federal Government;

(vi) The name of a pesticide which contains two or more principal active ingredients if the name suggests one or more but not all such principal active ingredients even though the names of the other ingredients are stated elsewhere in the labeling;

(vii) A true statement used in such a way as to give a false or misleading impression to the purchaser;

(viii) Label disclaimers which negate or detract from labeling statements required under the Act and these regulations;

(ix) Claims as to the safety of the pesticide or its ingredients, including statements such as "safe," "nonpoisonous," "noninjurious," "harmless" or "nontoxic to humans and pets" with or without such a qualifying phrase as "when used as directed"; and

(x) Non-numerical and/or comparative statements on the safety of the product, including but not limited to:

(A) "Contains all natural ingredients";

(B) "Among the least toxic chemicals known"

(C) "Pollution approved"

(6) *Final printed labeling.* (i) Except as provided in paragraph (a)(6)(ii) of this section, final printed labeling must be submitted and accepted prior to registration. However, final printed labeling need not be submitted until draft label texts have been provisionally accepted by the Agency.

(ii) Clearly legible reproductions or photo reductions will be accepted for unusual labels such as those silk-screened directly onto glass or metal containers or large bag or drum labels. Such reproductions must be of microfilm reproduction quality.

(b) *Name, brand, or trademark.* (1) The name, brand, or trademark under which the pesticide product is sold shall appear on the front panel of the label.

(2) No name, brand, or trademark may appear on the label which:

(i) Is false or misleading, or

(ii) Has not been approved by the Administrator through registration or supplemental registration as an additional name pursuant to § 162.6(b)(4).

(c) Name and address of producer, registrant, or person for whom produced. An unqualified name and address given on the label shall be considered as the name and address of the producer. If the registrant's name appears on the label and the registrant is not the producer, or if the name of the person for whom the pesticide was produced appears on the label, it must be qualified by appropriate wording such as "Packed for * * *," "Distributed by * * *," or "Sold by * * *" to show that the name is not that of the producer.

(d) *Net weight or measure of contents.* (1) The net weight or measure of content shall be exclusive of wrappers or other materials and shall be the average content unless explicitly stated as a minimum quantity.

(2) If the pesticide is a liquid, the net content statement shall be in terms of liquid measure at 68° F (20°C) and shall be expressed in conventional American units of fluid ounces, pints, quarts, and gallons.

(3) If the pesticide is solid or semisolid, viscous or pressurized, or is a mixture of liquid and solid, the net content statement shall be in terms of weight expressed as avoirdupois pounds and ounces.

(4) In all cases, net content shall be stated in terms of the largest suitable units, i.e., "1 pound 10 ounces" rather than "26 ounces."

(5) In addition to the required units specified, net content may be expressed in metric units.

(6) Variation above minimum content or around an average is permissible only to the extent that it represents deviation unavoidable in good manufacturing practice. Variation below a stated minimum is not permitted. In no case shall the average content of the packages in a shipment fall below the stated average content.

(e) *Product registration number.* The registration number assigned to the pesticide product at the time of registration shall appear on the label, preceded by the phrase "EPA Registration No.," or the phrase "EPA Reg. No." The registration number shall be set in type of a size and style similar to other print on that part of the label on which it appears and shall run par-

llel to it. The registration number nd the required identifying phrase hall not appear in such a manner as o suggest or imply recommendation r endorsement of the product by the gency.

(f) *Producing establishments registration number.* The producing establishment registration number preceded by the phrase "EPA Est.", of the inal establishment at which the product was produced may appear in any uitable location on the label or immediate container. It must appear on the wrapper or outside container of the package if the EPA establishment registration number on the immediate container cannot be clearly read hrough such wrapper or container.

(g) *Ingredient statement*—(1) *General.* The label of each pesticide product must bear a statement which contains he name and percentage by weight of each active ingredient, the total percentage by weight of all inert ingredients; and if the pesticide contains arsenic in any form, a statement of the percentages of total and water-soluble arsenic calculated as elemental arsenic. The active ingredients must be designated by the term "active ingredients" and the inert ingredients by the term "inert ingredients," or the singular forms of these terms when appropriate. Both terms shall be in the same type size, be aligned to the same margin and be equally prominent. The statement "Inert Ingredients, none" is not required for pesticides which contain 100 percent active ingredients. Unless the ingredient statement is a complete analysis of the pesticide, the term "analysis" shall not be used as a heading for the ingredient statement.

(2) *Position of ingredient statement.* (i) The ingredient statement is normally required on the front panel of the label. If there is an outside container or wrapper through which the ingredient statement cannot be clearly read, the ingredient statement must also appear on such outside container or wrapper. If the size or form of the package makes it impracticable to place the ingredient statement on the front panel of the label, permission may be granted for the ingredient statement to appear elsewhere.

(ii) The text of the ingredient statement must run parallel with other text on the panel on which it appears, and must be clearly distinguishable from and must not be placed in the body of other text.

(3) *Names to be used in ingredient statement.* The name used for each ingredient shall be the accepted common name, if there is one, followed by the chemical name. The common name may be used alone only if it is well known. If no common name has been established, the chemical name alone shall be used. In no case will the use of a trademark or proprietary name be permitted unless such name has been accepted as a common name by the Administrator under the authority of Section 25(c)(6).

(4) *Statements of percentages.* The percentages of ingredients shall be stated in terms of weight-to-weight. The sum of percentages of the active and the inert ingredients shall be 100. Percentages shall not be expressed by a range of values such as "22-25%." If the uses of the pesticide product are expressed as weight of active ingredient per unit area, a statement of the weight of active ingredient per unit volume of the pesticide formulation shall also appear in the ingredient statement.

(5) *Accuracy of stated percentages.* The percentages given shall be as precise as possible reflecting good manufacturing practice. If there may be unavoidable variation between manufacturing batches, the value stated for each active ingredient shall be the lowest percentage which may be present.

(6) *Deterioration.* Pesticides which change in chemical composition significantly must meet the following labeling requirements:

(i) In cases where it is determined that a pesticide formulation changes chemical composition significantly, the product must bear the following statement in a prominent position on the label: "Not for sale or use after [date]."

(ii) The product must meet all label claims up to the expiration time indicated on the label.

(7) *Inert ingredients.* The Administrator may require the name of any

inert ingredient(s) to be listed in the ingredient statement if he determines that such ingredient(s) may pose a hazard to man or the environment.

(h) *Warnings and precautionary statements.* Required warnings and precautionary statements concerning the general areas of toxicological hazard including hazard to children, environmental hazard, and physical or chemical hazard fall into two groups; those required on the front panel of the labeling and those which may appear elsewhere. Specific requirements concerning content, placement, type size, and prominence are given below.

(1) *Required front panel statements.* With the exception of the child hazard warning statement, the text required on the front panel of the label is determined by the Toxicity Category of the pesticide. The category is assigned on the basis of the highest hazard shown by any of the indicators in the table below:

Hazard indicators	Toxicity categories			
	I	II	III	IV
Oral LD_{50}	Up to and including 50 mg/kg.	From 50 thru 500 mg/kg.	From 500 thru 5000 mg/kg.	Greater than 5000 mg/kg.
Inhalation LC_{50}	Up to and including .2 mg/liter.	From .2 thru 2 mg/liter.	From 2 thru 20 mg/liter.	Greater than 20 mg/liter.
Dermal LD_{50}	Up to and including 200 mg/kg.	From 200 thru 2000.	From 2,000 thru 20,000.	Greater than 20,000.
Eye effects	Corrosive; corneal opacity not reversible within 7 days.	Corneal opacity reversible within 7 days; irritation persisting for 7 days.	No corneal opacity; irritation reversible within 7 days.	No irritation.
Skin effects	Corrosive.	Severe irritation at 72 hours.	Moderate irritation at 72 hours.	Mild or slight irritation at 72 hours.

(i) *Human hazard signal word*—(A) *Toxicity Category I.* All pesticide products meeting the criteria of Toxicity Category I shall bear on the front panel the signal word "Danger." In addition if the product was assigned to Toxicity Category I on the basis of its oral, inhalation or dermal toxicity (as distinct from skin and eye local effects) the word "Poison" shall appear in red on a background of distinctly contrasting color and the skull and crossbones shall appear in immediate proximity to the word "poison."

(B) *Toxicity Category II.* All pesticide products meeting the criteria of Toxicity Category II shall bear on the front panel the signal word "Warning."

(C) *Toxicity Category III.* All pesticide products meeting the criteria of Toxicity Category III shall bear on the front panel the signal word "Caution."

(D) *Toxicity Category IV.* All pesticide products meeting the criteria of Toxicity Category IV shall bear on the front panel the signal word "Caution."

(E) *Use of signal words.* Use of any signal word(s) associated with a higher Toxicity Category is not permitted except when the Agency determines that such labeling is necessary to prevent unreasonable adverse effects on man or the environment. In no case shall more than one human hazard signal word appear on the front panel of a label.

(ii) *Child hazard warning.* Every pesticide product label shall bear on the front panel the statement "keep out of reach of children." Only in cases where the likelihood of contact with children during distribution, marketing, storage or use is demonstrated by the applicant to be extremely remote, or if the nature of the pesticide is such that it is approved for use on infants or small children, may the Administrator waive this requirement.

(iii) *Statement of practical treatment*—(A) *Toxicity Category I.* A statement of practical treatment (first aid or other) shall appear on the front panel of the label of all pesticides falling into Toxicity Category I on the basis of oral, inhalation or dermal toxicity. The Agency may, however, permit reasonable variations in the

cement of the statement of practi- treatment is some reference such "See statement of practical treat- nt on back panel" appears on the nt panel near the word "Poison" l the skull and crossbones.

(B) *Other toxicity categories.* The tement of practical treatment is not uired on the front panel except as scribed in paragraph (h)(1)(iii)(A) of is section. The applicant may, how- er, include such a front panel state- nt at his option. Statements of actical treatment are, however, re- ired elsewhere on the label in cord with paragraph (h)(2) of this ction if they do not appear on the ont panel.

(iv) *Placement and prominence.* All e require front panel warning state- ents shall be grouped together on e label, and shall appear with suffi- ent prominence relative to other ont panel text and graphic material make them unlikely to be over- oked under customary conditions of urchase and use. The following table ows the minimum type size require- ents for the front panel warning atements on various sizes of labels:

Size of label front panel in square inches	Points	
	Required signal word, all capitals	Keep out of reach of Children
5 and under	6	6
Above 5 to 10	10	6
Above 10 to 15	12	8
Above 15 to 30	14	10
Over 30	18	12

(2) *Other required warnings and precautionary statements.* The warnings and precautionary statements as required below shall appear together on the label under the general heading "Precautionary Statements" and under appropriate subheadings of "Hazard to Humans and Domestic Animals," "Environmental Hazard" and "Physical or Chemical Hazard."

(i) *Hazard to humans and domestic animals.* (A) Where a hazard exists to humans or domestic animals, precautionary statements are required indicating the particular hazard, the route(s) of exposure and the precautions to be taken to avoid accident, injury or damage. The precautionary paragraph shall be immediately preceded by the appropriate hazard signal word.

(B) The following table depicts typical precautionary statements. These statements must be modified or expanded to reflect specific hazards.

Toxicity category	Precautionary statements by toxicity category	
	Oral, inhalation, or dermal toxicity	Skin and eye local effects
	Fatal (poisonous) if swallowed (inhaled or absorbed through skin). Do not breathe vapor (dust or spray mist). Do not get in eyes, on skin, or on clothing. (Front panel statement of practical treatment required.)	Corrosive, causes eye and skin damage. (or skin irritation). Do not get in eyes, on skin, or on clothing. Wear goggles or face shield and rubber gloves when handling. Harmful or fatal if swallowed. (Appropriate first aid statement required.)
	May be fatal if swallowed (inhaled or absorbed through the skin). Do not breathe vapors (dust or spray mist). Do not get in eyes, on skin, or on clothing. (Appropriate first aid statements required.)	Causes eye (and skin) irritation. Do not get in eyes, on skin, or on clothing. Harmful if swallowed. (Appropriate first aid statement required.)
	Harmful if swallowed (inhaled or absorbed through the skin). Avoid breathing vapors (dust or spray mist). Avoid contact with skin (eyes or clothing). (Appropriate first aid statement required.)	Avoid contact with skin, eyes or clothing. In case of contact immediately flush eyes or skin with plenty of water. Get medical attention if irritation persists.
v	(No precautionary statements required.)	(No precautionary statements required.)

(ii) *Environmental hazards.* Where a hazard exists to non target organisms excluding humans and domestic animals, precautionary statements are required stating the nature of the hazard and the appropriate precautions to avoid potential accident, injury or damage. Examples of the hazard statements and the circumstances under which they are required follow:

(A) If a pesticide intended for outdoor use contains an active ingredient with a mammalian acute oral LD_{50} of 100 or less, the statement "This Pesticide is Toxic to Wildlife" is required.

(B) If a pesticide intended for outdoor use contains an active ingredient with a fish acute LC_{50} of 1 ppm or less, the statement "This Pesticide is Toxic to Fish" is required.

(C) If a pesticide intended for outdoor use contains an active ingredient with an avian acute oral LD_{50} of 100 mg/kg or less, or a subacute dietary LC_{50} of 500 ppm or less, the statement "This Pesticide is Toxic to Wildlife" is required.

(D) If either accident history or field studies demonstrate that use of the pesticide may result in fatality to birds, fish or mammals, the statement "This pesticide is extremely toxic to wildlife (fish)" is required.

(E) For uses involving foliar application to agricultural crops, forests, or shade trees, or for mosquito abatement treatments, pesticides toxic to pollinating insects must bear appropriate label cautions.

(F) For all outdoor uses other than aquatic applications the label must bear the caution "Keep out of lakes, ponds or streams. Do not contaminate water by cleaning of equipment or disposal of wastes."

(iii) *Physical or chemical hazards.* Warning statements on the flammability or explosive characteristics of the pesticide are required as follows:

Flash point	Required text
(A) Pressurized Containers	
Flash point at or below 20° F, if there is a flashback at any valve opening	Extremely flammable. Contents under pressure. Keep away from fire, sparks, and heated surfaces. Do not puncture or incinerate container. Exposure to temperatures above 130° F may cause bursting.
Flash point above 20° F and not over 80° F or if the flame extension is more than 18 in long at a distance of 6 in from the flame	Flammable. Contents under pressure. Keep away from heat, sparks, and open flame. Do not puncture or incinerate container. Exposure to temperatures above 130° F may cause bursting.
All other pressurized containers	Contents under pressure. Do not use or store near heat or open flame. Do not puncture or incinerate container. Exposure to temperatures above 130° F may cause bursting.
(B) Nonpressurized Containers	
At or below 20° F	Extremely flammable. Keep away from fire, sparks, and heated surfaces.
Above 20° F and not over 80° F	Flammable. Keep away from heat and open flame.
Above 80° F and not over 150° F	Do not use or store near heat or open flame.

(i) *Directions for Use—(1) General requirements—(i) Adequacy and clarity of directions.* Directions for use must be stated in terms which can be easily read and understood by the average person likely to use or to supervise the use of the pesticide. When followed, directions must be adequate to protect the public from fraud and from personal injury and to prevent unreasonable adverse effects on the environment.

(ii) *Placement of directions for use.* Directions may appear on any portion of the label provided that they are conspicuous enough to be easily read by the user of the pesticide product. Directions for use may appear on printed or graphic matter which accompanies the pesticide provided that:

(A) If required by the Agency, such printed or graphic matter is securely attached to each package of the pesticide, or placed within the outside wrapper or bag;

(B) The label bears a reference to the directions for use in accompanying leaflets or circulars, such as "See directions in the enclosed circular:" and

(C) The Administrator determines that it is not necessary for such directions to appear on the label.

(iii) *Exceptions to requirement for direction for use—*(A) Detailed directions for use may be omitted from labeling of pesticides which are intended

(44)

use only by manufacturers of prod-
s other than pesticide products in
ir regular manufacturing processes,
ovided that:

1) The label clearly shows that the
oduct is intended for use only in
nufacturing processes and specifies
e type(s) of products involved.

2) Adequate information such as
chnical data sheets or bulletins, is
ailable to the trade specifying the
pe of product involved and its
oper use in manufacturing process-

(3) The product will not come into
ie hands of the general public except
ter incorporation into finished prod-
cts; and

(4) The Administrator determines
iat such directions are not necessary
) prevent unreasonable adverse ef-
ects on man or the environment.

(B) Detailed directions for use may
e omitted from the labeling of pesti-
ide products for which sale is limited
o physicians, veterinarians, or drug-
ists, provided that:

(1) The label clearly states that the
roduct is for use only by physicians
r veterinarians;

(2) The Administrator determines
hat such directions are not necessary
o prevent unreasonable adverse ef-
fects on man or the environment; and

(3) The product is also a drug and
regulated under the provisions of the
Federal Food, Drug and Cosmetic Act.

(C) Detailed directions for use may
be omitted from the labeling of pesti-
cide products which are intended for
use only by formulators in preparing
pesticides for sale to the public, pro-
vided that:

(1) There is information readily
available to the formulators on the
composition, toxicity, methods of use,
applicable restrictions or limitations,
and effectiveness of the product for
pesticide purposes;

(2) The label clearly states that the
product is intended for use only in
manufacturing, formulating, mixing,
or repacking for use as a pesticide and
specifies the type(s) of pesticide prod-
ucts involved;

(3) The product as finally manufac-
tured, formulated, mixed, or repack-
aged is registered; and

(4) The Administrator determines
that such directions are not necessary
to prevent unreasonable adverse ef-
fects on man or the environment.

(2) *Contents of Directions for Use.*
The directions for use shall include
the following, under the headings "Di-
rections for Use":

(i) The statement of use classifica-
tion as prescribed in 162.10(j) immedi-
ately under the heading "Directions
for Use."

(ii) Immediately below the state-
ment of use classification, the state-
ment "It is a violation of Federal law
to use this product in a manner incon-
sistent with its labeling."

(iii) The site(s) of application, as for
example the crops, animals, areas, or
objects to be treated.

(iv) The target pest(s) associated
with each site.

(v) The dosage rate associated with
each site and pest.

(vi) The method of application, in-
cluding instructions for dilution, if re-
quired, and type(s) of application ap-
paratus or equipment required.

(vii) The frequency and timing of ap-
plications necessary to obtain effective
results without causing unreasonable
adverse effects on the environment.

(viii) Specific limitations on reentry
to areas where the pesticide has been
applied, meeting the requirements
concerning reentry provided by 40
CFR Part 170.

(ix) Specific directions concerning
the storage and disposal of the pesti-
cide and its container, meeting the re-
quirements of 40 CFR Part 165. These
instructions shall be grouped and
appear under the heading "Storage
and Disposal." This heading must be
set in type of the same minimum sizes
as required for the child hazard warn-
ing (See Table in § 162.10(h)(1)(iv).)

(x) Any limitations or restrictions on
use required to prevent unreasonable
adverse effects, such as:

(A) Required intervals between ap-
plication and harvest of food or feed
crops.

(B) Rotational crop restrictions.

(C) Warnings as required against use
on certain crops, animals, objects, or
in or adjacent to certain areas.

(D) [Reserved]

(E) For restricted use pesticides, a
statement that the pesticide may be
applied under the direct supervision of
a certified applicator who is not phys-
ically present at the site of application
but nonetheless available to the
person applying the pesticide, unless
the Agency has determined that the
pesticide may only be applied under
the direct supervision of a certified ap-
plicator who is physically present.

(F) Other pertinent information
which the Administrator determines
to be necessary for the protection of
man and the environment.

(j) *Statement of Use Classification.*
By October 22, 1976, all pesticide prod-
ucts must bear on their labels a state-
ment of use classification as described
in paragraphs (j)(1) and (2) of this
section. Any pesticide product for
which some uses are classified for gen-
eral use and others for restricted use
shall be separately labeled according
to the labeling standards set forth in
this subsection, and shall be marketed
as separate products with different
registration numbers, one bearing di-
rections only for general use(s) and
the other bearing directions for re-
stricted use(s) except that, if a product
has both restricted use(s) and general
use(s), both of these uses may appear
on a product labeled for restricted use.
Such products shall be subject to the
provisions of § 162.10(j)(2).

(1) *General Use Classification.* Pesti-
cide products bearing directions for
use(s) classified general shall be la-
beled with the exact words "General
Classification" immediately below the
heading "Directions for Use." And ref-
erence to the general classification
that suggests or implies that the gen-
eral utility of the pesticide extends
beyond those purposes and uses con-
tained in the Directions for Use will be
considered a false or misleading state-
ment under the statutory definitions
of misbranding.

(2) *Restricted Use Classification.*
Pesticide products bearing direction
for use(s) classified restricted shall
bear statements of restricted use clas-
sification on the front panel as de-
scribed below:

(i) *Front panel statement of restrict-
ed use classification.* (A) At the top of
the front panel of the label, set in type
of the same minimum sizes as required
for human hazard signal words (see
table in § 162.10(h)(1)(iv)), and appear-
ing with sufficient prominence relative
to other text and graphic material on
the front panel to make it unlikely to
be overlooked under customary condi-
tions of purchase and use, the state-
ment "Restricted Use Pesticide" shall
appear.

(B) Directly below this statement on
the front panel, a summary statement
of the terms of restriction imposed as
a precondition to registration shall
appear. If use is restricted to certified
applicators, the following statement is
required: "For retail sale to and use
only by Certified Applicators or per-
sons under their direct supervision and
only for those uses covered by the Cer-
tified Applicator's certification." If,
however, other regulatory restrictions
are imposed, the Administrator will
define the appropriate wording for the
terms of restriction by regulation.

(k) Advertising. [Reserved]

[40 FR 28268, July 3, 1975; 40 FR 32329, Aug. 1, 1975; 40 FR 36571, Aug. 21, 1975, as amended at 43 FR 5786, Feb. 9, 1978]

LABELING REQUIREMENTS OF THE FIFRA, AS AMENDED (REFER TO THE SAMPLE LABELS FOLLOWING)

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
1	Product name	All products	Front panel	Center front panel	
2	Company name and address	All products	None	Bottom front panel or end of label text	If registrant is not the producer, must be qualified by "Packed for . . .," "Distributed by. . .," etc.
3	Net contents	All products	None	Bottom front panel or end of label text	May be in metric units in addition to U.S. units
4	EPA Est. No.	All products	None	Front panel	Must be in similar type size and run parallel to other type.
5	EPA Reg. No.	All products	None	Front panel, immediately before or following Reg. No.	May appear on the container instead of the label.
6A	Ingredients statement	All products	Front panel	Immediately following product name	Text must run parallel with other text on the panel.
6B	Pounds/gallon statement	Liquid products where dosage given as lbs. ai/unit area	Front panel	Directly below the main ingredients statement	
7	Front panel precautionary statements	All products	Front panel		All front panel precautionary statements must be grouped together, preferably blocked.
7A	Keep Out of Reach of Children (Child hazard warning)	All products	Front panel	Above signal word	Note type size requirements.
7B	Signal word	All products	Front panel	Immediately below child hazard warning	Note type size requirements.

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
7C	Skull & crossbones and word POISON (in red)	All products which are Category I based on oral, dermal, or inhalation toxicity	Front panel	Both in close proximity to signal word	
7D	Statement of practical treatment	All products in Categories I, II, and III	Category I: Front panel unless referral statement is used. Others: Grouped with side panel precautionary statements.	Front panel for all.	
7E	Referral statement	All products where precautionary labeling appears on other than front panel.	Front panel		
8	Side/back panel precautionary statements	All products	None	Top or side of back panel preceding directions for use	Must be grouped under the headings in 8A, 8B, and 8C; preferably blocked.
8A	Hazards to humans and domestic animals	All products in Categories I, II, and III	None	Same as above	Must be preceded by appropriate signal word.
8B	Environmental hazards	All products	None	Same as above	Environmental hazards include bee caution where applicable.

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
8C	Physical or chemical hazards	All pressurized products, others with flash points under 150°F	None	Same as above	
9A	Restricted block	All restricted products	Top center of front panel	Preferably blocked	Includes a statement of the terms of restriction. The words "RESTRICTED USE PESTICIDE" must be same type size as signal word.
9C	Misuse statement	All products	Immediately following statement of classification or ahead of directions for use		
10A	Re-entry statement	All cholinesterase inhibitors	In the directions for use	Immediately after misuse statement	
10C	Storage and disposal block	All products	In the directions for use	Immediately before specific directions for use or at the end of directions for use	Must be set apart and clearly distinguishable from from other directions for use.
10D U.S.	Directions for use	All products	None	None	May be in metric as well as U.S. units

RESTRICTED USE PESTICIDE

PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS
(& DOMESTIC ANIMALS)
DANGER (8A)

ENVIRONMENTAL HAZARDS (8B)

PHYSICAL OR CHEMICAL HAZARDS (8C)

DIRECTIONS FOR USE (10D)

[illegible] a violation of Federal law to use product in a manner inconsistent with its labeling.

RE-ENTRY STATEMENT
(If Applicable) (10A)

CATEGORY OF APPLICATOR

STORAGE AND DISPOSAL (10C)

STORAGE

DISPOSAL

IF:

RESTRICTED USE PESTICIDE (9A)

FOR RETAIL SALE TO AND APPLICATION ONLY BY CERTIFIED APPLICATORS OR PERSONS UNDER THEIR DIRECT SUPERVISION

PRODUCT (1) NAME

ACTIVE INGREDIENT: _____ % (6A)
INERT INGREDIENTS: _____ %

TOTAL: 100.00 %

THIS PRODUCT CONTAINS _____ LBS OF _____ PER GALLON (6B)

KEEP OUT OF REACH OF CHILDREN (7A)

(7B) DANGER — POISON

(7C)

(7)

STATEMENT OF PRACTICAL TREATMENT (7D)

IF SWALLOWED _____
IF INHALED _____
IF ON SKIN _____
IF IN EYES _____

SEE SIDE PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS

MFG BY _____ (2)
TOWN, STATE _____
ESTABLISHMENT NO. _____ (4)
EPA REGISTRATION NO. _____ (5)

NET CONTENTS _____ (3)

CROP:

CROP:

CROP:

CROP:

CROP:

WARRANTY STATEMENT

Appendix V-3

PHYSICAL-CHEMICAL HAZARDS

Criteria	Required Label Statement
I. Pressurized Containers	
A. Flashpoint at or below 20°F; or if there is a flashback at any valve opening.	Extremely flammable. Contents under pressure. Keep away from fire, sparks, and heated surfaces. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
B. Flashpoint above 20°F and not over 80°F; or if the flame extension is more than 18 inches long at a distance of 6 inches from the valve opening.	Flammable. Contents under pressure. Keep away from heat, sparks, and flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
C. ALL OTHER PRESSURIZED CONTAINERS	Contents under pressure. Do not use or store near heat or open flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
II. Non-Pressurized Containers	
A. Flashpoint at or below 20°F.	Extremely flammable. Keep away from fire, sparks, and heated surfaces.
B. Flashpoint above 20°F and over 80°F.	Flammable. Keep away from heat and open flame.
C. Flashpoint over 80°F and not over 150°F.	Do not use or store near heat and open flame.
D. Flashpoint above 150°F.	None required.

Appendix V-5

STORAGE AND DISPOSAL INSTRUCTIONS FOR PESTICIDES

All products are required to bear specific label instructions about storage and disposal. Storage and disposal instructions must be grouped together in the directions for use portion of the label under the heading STORAGE AND DISPOSAL. Products intended solely for domestic use need not include the heading "STORAGE AND DISPOSAL." The STORAGE AND DISPOSAL heading must appear in the minimum type size listed below:

Size of label front panel in square inches	Required type size for the heading STORAGE AND DISPOSAL (all capitals)
10 and under	.6 point
Above 10 to 15	.8 point
Above 15 to 30	10 point
Over 30	12 point

Storage and disposal instructions must be set apart and clearly distinguishable from other directions for use. Blocking storage and disposal statements with a solid line is suggested as a means of increasing their prominence.

A. Storage Instructions:

All product labels are required to have appropriate storage instructions. Specific storage instructions are not prescribed. Each registrant must develop his own storage instructions, considering, when applicable, the following factors:

1. Conditions of storage that might alter the composition or usefulness of the pesticide. Examples could be temperature extremes, excessive moisture or humidity, heat, sunlight, friction, or contaminating substances or media.

2. Physical requirements of storage which might adversely affect the container of the product and its ability to continue to function properly. Requirements might include positioning of the container in storage, storage or damage due to stacking, penetration of moisture, and ability to withstand shock or friction.

3. Specifications for handling the pesticide container, including movement of container within the storage area, proper opening and closing procedures (particularly for opened containers), and measures to minimize exposure while opening or closing container.

Appendix V-4
(continued)

4. Instructions on what to do if the container is damaged in any way, or if the pesticide is leaking or has been spilled, and precautions to minimize exposure if damage occurs.

5. General precautions concerning locked storage, storage in original container only, and separation of pesticides during storage to prevent cross-contamination of other pesticides, fertilizer, food, and feed.

6. General storage instructions for household products should emphasize storage in original container and placement in locked storage areas.

B. Pesticide Disposal Instructions:

The label of all products, except those intended solely for domestic use, must bear explicit instructions about pesticide disposal. The statements listed below contain the exact wording that must appear on the label of these products:

1. The labels of all products, except domestic use, must contain the statement, "Do not contaminate water, food, or feed by storage or disposal."

2. Except those products intended solely for domestic use, the labels of all products that contain active ingredients appearing on the "Acutely Hazardous" Commercial Pesticide Products List (RCRA "E" List) at the end of this appendix or are assigned to Toxicity Category I on the basis of oral or dermal toxicity, skin or eye irritation potential, or Toxicity Category I or II on the basis of acute inhalation toxicity must bear the following pesticide disposal statement:

"Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance."

The labels of all products, except those intended for domestic use, containing active or inert ingredients that appear on the "Toxic" Commercial Pesticide Products List (RCRA "F" List) at the end of this appendix or presently meet any of the criteria in Subpart C, 40 CFR 261 for a hazardous waste must bear the following pesticide disposal statement:

"Pesticide wastes are toxic. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance."

Labels for all other products, except those intended for domestic use, must bear the following pesticide disposal statement:

"Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility."

3. Products intended for domestic use only must bear the following disposal statement: "Securely wrap original container in several layers of newspaper and discard in trash."

C. Container Disposal Instructions

The label of each product must bear container disposal instructions appropriate to the type of container.

1. All products intended for domestic use must bear one of the following container disposal statements:

Container Type	Statement
Non-aerosol products (bottles, cans, jars)	Do not reuse container (bottle, can, jar). Rinse thoroughly before discarding in trash.
Non-aerosol products (bags)	Do not reuse bag. Discard bag in trash.
Aerosol products	Replace cap and discard containers in trash. Do not incinerate or puncture.

2. The labels for all other products must bear container disposal instructions, based on container type, listed below:

Container Type	Statement
Metal containers (non-aerosol)	Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.
Plastic containers	Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.
Glass containers	Triple rinse (or equivalent). Then dispose of in a sanitary landfill or by other approved state and local procedures.

Appendix V-4
(continued)

Container Type	Statement
Fiber drums with liners	Completely empty liner by shaking and tapping sides and bottom to loosen clinging particles. Empty residue into application equipment. Then dispose of liner in a sanitary landfill or by incineration if allowed by state and local authorities. If drum is contaminated and cannot be reused[1], dispose of in the same manner.
Paper and plastic bags	Completely empty bag into application equipment. Then dispose of empty bag in a sanitary landfill or by incineration, or, if allowed by State and local authorities, by burning. If burned, stay out of smoke.
Compressed gas cylinders	Return empty cylinder for reuse (or similar wording).

[1]Manufacturer may replace this phrase with one indicating whether and how fiber drum may be reused.

2. The labels for all other products must bear container disposal instructions, based on container type, listed on the first page of this Appendix.

Appendix V-4
(continued)

Pesticides that are hazardous wastes under 40 CFR 261.33(e) and (f) when discarded.

"Acutely Hazardous" Commercial Pesticides (RCRA "E" List)
Active Ingredients, (no inerts):

Acrolein
Aldicarb
Aldrin
Allyl alcohol
Aluminum phosphide
4-Aminopyridine
Arsenic acid
Arsenic pentoxide
Arsenic trioxide
Calcium cyanide
Carbon disulfide
p-Chloroaniline
Cyanides (soluble cyanide salts, not specified elsewere)
Cyanogen chloride
2-Cyclohexyl-4,6-dinitrophenol
Dieldrin
O,O-Diethyl S-[2-ethylthio)ethyl] phosphorodithioate
(disulfoton, Di-Syston)
O,O-Diethyl O-pyrazinyl phosphorothioate (Zinophos)
Dimethoate
O,O-Dimethyl O-p-nitrophenyl phosphorothioate (methyl parathion)
4,6-Dinitro-o-cresol and salts
4,6-Dinitro-o-cyclohexylphenol
2,4 Dinitrophenol
Dinoseb
Endosulfan
Endothall
Endrin
Famphur
Fluoroacetamide
Heptachlor
Hexanethyl tetraphosphate
Hydrocyanic acid
Hydrogen cyanide
Methomyl
alpha-Naphthylthiourea (ANTU)
Nicotine and salts
Octamethylpyrophosphoramide (OMPA, schradan)
Parathion

Appendix V-4
(continued)

"Acutely Hazardous" Commercial Pesticides (RCRA "E" List)
Active Ingredients continued:

Phenylmercuric acetate (PMA)
Phorate
Potassium cyanide
Propargyl alcohol
Sodium azide
Sodium cyanide
Sodium fluoroacetate
Strychnine and salts
0,0,0,0-Tetraethyl dithiopyrophosphate (sulfotepp)
Tetraethyl pyrophosphate
Thallium sulfate
Thiofanox
Toxaphene
Warfarin
Zinc phosphide

There are currently no inert ingredients for commercial pesticides on the "Acutely Hazardous" List (RCRA "E" List).

"Toxic" Commercial Pesticide Products (RCRA "F" List)
Active Ingredients:

Acetone
Acrylonitrile
Amitrole
Benzene
Bis(2-ethylhexyl)pthalate
Cacodylic acid
Carbon tetrachloride
Chloral (hydrate)
Chlordane (technical)
Chlorobenzene
4-Chloro-m-cresol
Chloroform
o-Chlorophenol
4-Chloro-o-toluidine hydrochloride
Creosote
Cresylic acid
Cyclohexane
Decachlorooctahydro-1,3,4-metheno-2H-cyclobuta[c,d]-pentalen-2-one
(kepone, chlordecone)
1,2-Dibromo-3-chloropropane (DBCP)
Dibutyl phthalate
S-3,3-(Dichloroallyl diisopropylthiocarbamate (diallate, Avadex)
o-Dichlorobenzene
p-Dichlorobenzene
Dichlorodifluoromethane (Freon 12®)
3,5-Dichloro-N-(1,1-dimethyl-2-propynyl) benzamide (pronamide,Kerb)
Dichloro diphenyl dichloroethane (DDD)
Dichloro diphenyl trichloroethane (DDT)
Dichlorethyl ether
2,4-Dichlorophenoxyacetic, esters and salts (2,4-D)
1,2-Dichloropropane
1,3-Dichloropropane (Telone)
Dimethyl phthalate
Ethyl acetate
Ethyl 4,4'-dichlorobenzilate (chlorobenzilate)
Ethylene dibromide (EDB)
Ethylene dichloride
Ethylene oxide
Formaldehyde
Furfural
Hexachlorobenzene
Hexachlorocyclopentadiene
Hexachloroethane
Hydrofluoric acid

Appendix V-4
(continued)

"Toxic" Commercial Pesticide Products (RCRA "F" List)
Active Ingredients:

Isobutyl alcohol
Lead acetate
Lindane
Maleic hydrazide
Mercury
Methyl alcohol
Methyl bromide
Methyl chloride
2,2'-Methylenebis (3,4,6-trichlorophenol) (hexachlorophene)
Methylene chloride
Methyl ethyl ketone
4-Methyl-2-pentanone (methyl isobutyl ketone)
Naphthalene
Nitrobenzene
p-Nitrophenol
Pentachloroethane
Pentachloronitrobenzene (PCNB)
Pentaclorophenol
Phenol
Phosphorodithioic acid, 0,0-diethyl, methyl ester
Propylene dichloride
Pyridine
Resorcinol
Safrole
Selenium disulfide
Silvex
1,2,4,5-Tetrachlorobenzene
1,1,2,2-Tetrachloroethane
Tetrachloroethylene
2,3,4,6-Tetrachlorophenol
Thiram
Toluene
1,1,1-Trichloroethane
Trichloroethylene
Trichloromonofluoromethane (Freon 11®)
2,4,5-Trichlorophenol
2,4,6-Trichlorophenol
2,4,5-Trichlorophenoxyacetic acid (2,4,5-T)
Xylene

"Toxic" Commercial Pesticide Products (RCRA "F" List)
Inert Ingredients:

Acetone
Acetonitrile
Acetophenone
Acrylic acid
Aniline
Benzene
Chlorobenzene
Chloroform
Cyclohexane
Cyclohexanone
Dichlorodifluoromethane (Freon 12®)
Diethyl phthalate
Dimethylamine
Dimethyl phthalate
1,4-Dioxane
Ethylene oxide
Formaldehyde
Formic acid
Isobutyl alcohol
Meleic anhydride
Methyl alcohol (methanol)
Methyl ethyl ketone
Methyl methacrylate
Naphthalene
Saccharin and salts
Thiourea
Toluene
1,1,1-Trichloroethane
1,1,2-Trichloroethane
Trichlorofluoromethane (Freon 11®
Vinyl chloride
Xylene

Appendix V-F
(continued)

"Toxic" Commercial Pesticide Products (RCRA "F" List)
Inert Ingredients:

Acetone
Acetonitrile
Acetophenone
Acrylic acid
Aniline
Benzene
Chlorobenzene
Chloroform
Cyclohexane
Cyclohexanone
Dichlorodifluoromethane (Freon 12®)
Diethyl phthalate
Dimethylamine
Dimethyl phthalate
1,4-Dioxane
Ethylene oxide
Formaldehyde
Formic acid
Isobutyl alcohol
Meleic anhydride
Methyl alcohol (methanol)
Methyl ethyl ketone
Methyl methacrylate
Naphthalene
Saccharin and salts
Thiourea
Toluene
1,1,1-Trichloroethane
1,1,2-Trichloroethane
Trichlorofluoromethane (Freon 11®
Vinyl chloride
Xylene